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ENZI, KENNEDY SAY INSTITUTE OF MEDICINE REPORT POINTS TO NEED FOR FDA REFORM LEGISLATION TO ENHANCE DRUG SAFETY

Washington, D.C. - U.S. Senator Mike Enzi (R-Wyo.), Chairman of the Senate Health, Education, Labor and Pensions (HELP) Committee and Senator Edward M. Kennedy (D-Mass.), Ranking Member of the Committee, today's report by the Institute of Medicine (IOM) adds new urgency for Congress to act on reform legislation to give the Food and Drug Administration (FDA) better tools to protect and promote the public health.

"Families expect the FDA to keep tabs on the drugs on the market, to ensure continued safety, and to take appropriate action if new information demonstrates new risks that were not apparent when a drug was initially approved," Enzi said. "I am pleased to see that the IOM recommendations support changes to better ensure that these essential goals to protect public health are met."

Senator Kennedy said: "In this era of rapid medical progress, we need an FDA that can make sure that hopeful new drugs really help patients, not hurt**.** There are few more important duties of government than to keep people safe, and the IOM report suggests many useful reforms to help FDA fulfill that obligation, while ensuring that innovative new drugs reach the patients who need them without undue delay. I look forward to working with Chairman Enzi and the other members of the HELP Committee to implement needed reforms."

The blue ribbon panel's report, issued today, makes recommendations similar to many provisions of a bill introduced by Enzi and Kennedy, the "Enhancing Drug Safety and Innovation Act," S.3807. Changes recommended in both the IOM report and the Enzi-Kennedy bill include giving FDA the authority to: make label changes, order post-market studies, restrict Direct To Consumer Advertising, and restrict distribution.